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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/399,083	09/17/1999	DAVID CALDERWOOD	BBIC-043/A	1842

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EXAMINER

RAO, DEEPAK R

ART UNIT PAPER NUMBER

1624

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/399,083

Applicant(s)

CALDERWOOD ET AL.

Examiner

Deepak Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10, 11 and 46-52 are pending in the application.
- 4a) Of the above claim(s) 11 and 48-51 are withdrawn from consideration.
- 5) ☒ Claim(s) 52 is/~~are~~ allowed.
- 6) ☒ Claim(s) 1-8, 10, 46-47 are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

This office action is in response to the amendment filed on May 11, 2006.

Claims 1-8, 10-11, and 46-52 are pending in this application.

#### ***Election/Restrictions***

Applicant is reminded that the examination is based on the elected species (compound recited in claim 52) which reads on claims 1-8, 10, 46, 47 and 52.

Claims 11 and 48-51 are withdrawn from further consideration as being drawn to nonelected species (see MPEP §803.02) pursuant to 37 CFR 1.142(b).

Claims 1-8, 10, 46, 47 and 52 are considered to the extent readable on the examined subgenus, i.e., structural formula of claim 1 wherein ring A is phenyl; L is -NH-SO<sub>2</sub>-; j is 0; R<sub>3</sub> is substituted phenyl; R<sub>2</sub> is H; and R<sub>1</sub> is cyclopentyl, and **all** other definitions of the variables and the other species are withdrawn from consideration as being drawn to nonelected species.

#### ***Withdrawn Rejections/Objections:***

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

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***The following rejections are maintained:***

Claims 1-8, 10, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Calderwood et al., WO 98/41525. The reasons provided in the previous office action(s) are incorporated here by reference.

Applicant's arguments have been fully considered but they were not deemed to be persuasive. Applicant argues that 'the instant genus overlaps with the reference genus but the reference genus does not teach the instant genus *as a whole* (emphasis in original); the instant genus is significantly larger and there is no motivation in the reference for one of ordinary skill in the art to expand the genus as in the instant application'. This is not found to be persuasive. As explained in the previous office action, the instant claims are drawn to compounds that are structurally analogous to the reference compounds. In order to establish prima facie case of obviousness in genus-species or genus-subgenus situations, the following need to be established:

(A) Determine the scope and contents of the prior art – applicant submits that the instant genus overlaps with that of the reference genus. Further, the instant claims include many of the reference expressly disclosed compounds, which have been excluded from the instant claims, see the proviso statement in claim 1. Furthermore, applicant submits that 'the instant genus is significantly larger and encompasses many more compounds than the reference genus'. In the previous office action(s), it has been shown that the compounds of the instant claims differ from the reference disclosed compounds by only one variation, which variation is suggested to one of ordinary skill in the art because the skilled artisan would have the reasonable expectation that the structural analogs would have similar properties.

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(B) Ascertain the differences between the prior art and the claims at issue – It has been clearly established that the instant claims include compounds that are homologs and/or isomers of the reference expressly disclosed compounds. In other words, one of ordinary skill in the art need to make only one structural variation to arrive at a compound encompassed by the instant claims. MPEP § 2144.08 provides that “Consider any teachings of a “typical,” “preferred,” or “optimum” species or subgenus within the disclosed genus. If such a species or subgenus is structurally similar to that claimed, its disclosure may motivate one of ordinary skill in the art to choose the claimed species or subgenus from the genus, based on the reasonable expectation that structurally similar species usually have similar properties”.

(C) Determine the level of ordinary skill in the pertinent art – the reference teaches that the reference compounds are useful as pharmaceutical agents having tyrosine kinase inhibitor activity, which provides sufficient motivation to one of ordinary skill in the art to prepare the structural analogs of the reference compounds. MPEP § 2144.08 provides that “If the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species”.

See *Deuel*, 51 F.3d at 1558, 34 USPQ2d at 1214 (“Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.”). See *Payne*, 606 F.2d at 313, 203 USPQ at 254 (“An obviousness rejection based on similarity in chemical structure and function

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entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.”).

Applicant argues that ‘although the two genres overlap and the reference teaches use of the compounds as pharmaceutical agents, there is nothing in WO 98/41525 to suggest applicant’s genus’. However, the reference teaches a genus and expressly discloses compounds within the genus which are also encompassed by the instantly claimed genus. The instant claims exclude the reference disclosed compounds by an exclusionary proviso statement (see claim 1). The reference clearly suggests structurally similar compounds to those expressly disclosed in the reference which are encompassed by the reference genus, which are also encompassed by the instant claims. As indicated above and as explained in previous office actions, structural relationships provide requisite motivation to modify known compounds to obtain new compounds. The reference provides such motivation and suggests to one of ordinary skill in the art to prepare other compounds encompassed by the reference genus.

Applicant’s argument that ‘the reference discloses other compounds (such as examples 285-289, etc.) that are not encompassed by the instant genus and that the reference does not anticipate the applicant’s genus as a whole’ has been considered but not found to be persuasive. As established above and in the previous office action(s), the reference teaches a genus, expressly discloses several compounds and suggests the corresponding structural analogs (homologs, isomers, or compounds having substituents which are disclosed as equivalents), which is sufficient to establish a *prima facie* case of obviousness.

***Allowable Subject Matter***

Claim 52 is allowed. (The reasons provided in the previous office action are incorporated here by reference).

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Deepak Rao', with a stylized flourish at the end.

**Deepak Rao**  
**Primary Examiner**  
**Art Unit 1624**

July 24, 2006